REMARKS

Applicants propose not to amend any claims by this response.

Claims 18 to 21 were previously cancelled,

Claims 1-17 and 22-26 are pending in the application.

Allowable Subject Matter

Applicants acknowledge the Examiner's allowance of Claims 17, 23-25.

The Office Action dated July 9, 2009 indicated that claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants thank the Examiner for the recognition of allowability of claim 10.

Claims Rejections – 35 USC § 103

Claims 1-9, 11-16, 19, 22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,632,732 to Szabo et al. ("Szabo") in view of US Patent No. 5,509,907 to Bevilacqua ("Bevilacqua").

These rejections are respectfully traversed.

Of the claims rejected, claims 1 and 5 are independent, with the remaining claims dependent thereon.

Claim 1 is directed to a safety needle assembly and recites, among other things:

said shield comprising at least one support wall, and a channel mounted to said support wall, said channel having a top wall and opposed first and second sidewalls extending from said top wall, and at least one resiliently deflectable cannula finger lock projecting from said first sidewall angularly toward said top wall,

wherein said channel can be selectively mounted to said support wall in one of a plurality of orientations in relation to one another.

Claim 5 is directed to a safety needle assembly and recites, among other things: *said shield comprising at least one support wall, and a channel mounted to said support wall, said channel having a top wall and opposed first and second sidewalls extending from said top wall, and at least one resiliently deflectable cannula finger lock,*

wherein said top wall of said channel comprises mounting structure for mounting said channel to said support wall, whereby said channel can be disposed in either a first orientation or in a second orientation relative to said support wall for altering positions of said channel relative to said needle cannula.

Applicants submit that Szabo fails to disclose teach or suggest at least the claimed features of at least one resiliently deflectable cannula finger lock.

The Examiner takes the position in that it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the shield of Szabo to include a cannula finger lock, as taught by Bevilacqua.

The final office action dated July 9, 2009 states:

> "The examiner feels that Bevilacqua provides proper motivation and a benefit for adding a cannula finger lock to a needle shield since it would prevent the cannula from being accidentally released. One of ordinary skill in the art would understand that the cannula finger lock would provide an extra benefit to any needle shielding device that lacked such a structure (i.e. Szabo). The examiner also feels that the cannula lock wouldn't be redundant to the device of Szabo since the cannula lock would provide an extra locking element to ensure the needle is locked into the shield."

In the absence of hindsight, one skilled in the art would not have been motivated by Szabo to look at or for inclusion of at least one resiliently deflectable cannula finger lock, and thus would have no reason to look to the Bevilacqua reference.

In fact Szabo teaches away from the addition of a permanent locking feature such as a resiliently deflectable cannula finger lock.

Furthermore the addition of at least one resiliently deflectable cannula finger lock to the needle shield of Szabo changes the principle of operation, and destroys the function of the Szabo device.

Szabo discloses a cylindrical shield and coaxially aligned latch, in which neither the shield (34) nor latch (45) engages the needle cannula (See Figs 7 and 8 reproduced below).

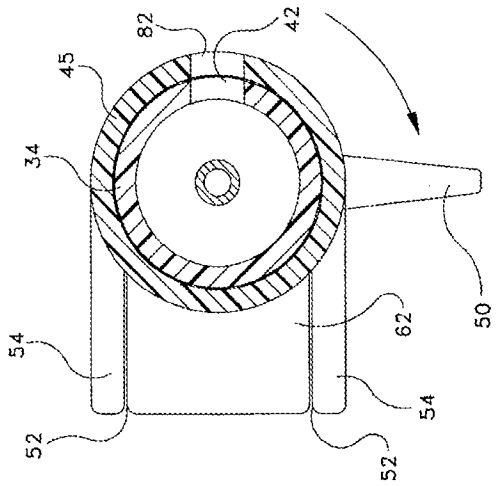

FIG. 8

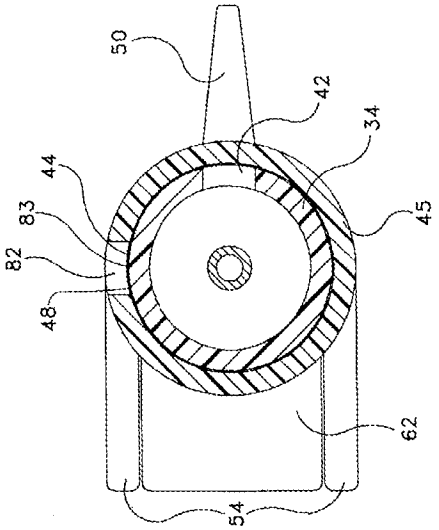

FIG. 7

Thus Szabo device relies on a reversible annular rotation of latch (45) relative to shield (34) to cause a misalignment of elongate slots (82) and (42) in order to lock the cannula within shield (34).

Szabo discloses several benefits of the shield over the existing art (see Col. 3 lines 11 to 15 shown below).

> In a hospital pharmacy type usage, a practitioner may open the shield to fill a syringe attached to the needle assembly of the invention, then close and relatch the shield for transportation to a remote location for administration to a patient. Anyone encountering the filled and reshielded syringe with the shielded needle assembly of the invention can readily visually ascertain whether or not the shield is merely closed or latched and unlikely to inadvertently be opened to expose the needle by simply observing the opening in the latch. The ability to visually ascertain the latched or unlatched state of the assembly of the invention is important to service personnel who may encounter an improperly disposed syringe in the course of the work.

These benefits include for example:

(1) The ability to reuse, reshield and relatch the shield, by reversibly rotating the latch around the shield from the latched (Fig.7) to unlatched position (Fig.8) and back to the latched position.

(2) The ability for the user to readily visually ascertain if the shield is open or closed (hence is the cannula safely shielded) by looking at the alignment of the elongated slots.

In regard to benefit (1) Szabo teaches away from the use of a permanent locking mechanism for the shield which prevents reuse, reshielding and relatching of the shield.

In contrast, Bevilacqua discloses a syringe needle guard assembly which provides a needle locking structure to permanently lock the needle within the guard assembly and prevent removal or reuse of the guard assembly (see Col. 2 lines 3 to 7 and Col. 3 lines 55 to 59 shown below, emphasis added).

> In addition, the syringe needle guard assembly of this invention provides structure for guiding the syringe needle laterally into and out of a needle guard while providing for selectively and permanently retaining the needle outlet portion within the needle guard.
>
> A locking means, generally designated as 60 (FIGS. 1-5, 9 and 10), is provided in needle guard 12 to allow needle guard 12 to be permanently secured in a guard position over outlet needle portion 22 to prevent removal of guard 12 from the guard position over needle portion 22 in guard 12.

In regard to benefit (2) the incorporation of a secondary locking element such as at least one resiliently deflectable cannula finger lock inside the shield of Szabo would destroy the ability for the user to readily visually ascertain if the shield is open or closed by looking at the alignment of the elongated slots.

The Examiner should also note, according to MPEP §2143.01 Section VI, that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Furthermore, according to MPEP §2143.01 Section V, that if a proposed modification would render the prior art invention modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Thus the addition of a permanent locking mechanism such as at least one resiliently deflectable cannula finger to the shield would prevent the reuse of a shield and render the visual indication of shielding moot thereby changing the principle of operation of Szabo.

The final office action dated July 9, 2009 further states:

> "The examiner further relies on MPEP and the recent KSR case when dealing with combining structural elements that are taught in the prior art. See MPEP section 2141 and ["In United States v. Adams, . . . [tlhe Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." Id. at -, 82"

Applicants respectfully submit that the examiner proposes the addition of a second "redundant" locking element (a cannula finger lock) to the device of Szabo and not a substitution of an element.

The final office action dated July 9, 2009 also states:

> "USPQ2d at 1395. (2) "In Anderson 's-Black Rock, Inc. v. Pavement Salvage Co.,. . . [tlhe two [pre-existing elements] in combination did no more than they would in separate, sequential operation."ld. at -, 82 USPQ2d at 1395. (3) "[lln Sakraida v. AG Pro, Inc., the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious."] MPEP section 21410.3 - "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR International Co. v. Teleflex Inc., 550 U .S. -, -, 82 USPQ2d 1385, 1397 (2007). "[lln many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into accounts "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. at -, 82 USPQ2d at 1396.

Applicants submit that the proposed modification of the shield of Szabo to include a cannula finger lock, as taught by Bevilacqua would prevent the Szabo needle shield element from performing the same function it had been known to perform.

For these reasons, applicants submit that independent claim 1 and dependent claims 2-4 10-16, and independent claim 5 and dependent claims 6-9 and 26, are patentable over the cited references.

Double Patenting Rejection

The Examiner rejected claims 1 and 5 under the doctrine of obviousness-type double patenting, as being unpatentable over claims 1 and 6 of U.S. Patent No. 7,220,249.

Applicant will file a Terminal Disclaimer if warranted, upon allowance of the claims, which addresses this rejection.

Conclusion

In view of the remarks herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicant's agent at the telephone number set forth below.

Respectfully submitted,

/Mark Lindsey/

Mark Lindsey
Registration No. 52,515
Agent for Applicant(s)
201 847 6262

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Becton, Dickinson and Company
1 Becton Drive, MC110
Franklin Lakes, New Jersey 07417-1880

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